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Butler Snow LLP is a full-service law firm with more than 350 attorneys and advisors who collaborate across a network of 27 offices in the USA, Europe and Asia. Butler Snow has a long history of successfully defending product liability claims on a regional and national basis. The firm represents manufacturers, distributors and service providers from an array of industries, including leading pharmaceutical and medical device companies, automotive and recreational vehicle manufacturers, and manufacturers of agricultural and industrial chemicals. Butler Snow's product liability litigators are regularly called upon to lead trial teams in some of the most challenging jurisdictions nationwide. For more information, visit www.butlersnow.com or follow the firm on Twitter @Butler_Snow.

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Identifying the Product in a Design Defect Case

In some design defect cases, the identity of the product decides the case. When a plaintiff seeks to prove there is a safer alternative design, the design must be for the same product. If it is not for the same product, the alternative cannot be used to prove that the defendant's product is defective. For that reason, product identity has played a role in product liability law since its earliest days. It has become increasingly more important with the advent of statutes requiring proof of a safer alternative design.

Common law product liability does not necessarily require proof of a safer alternative design to establish a defect. There may be, for example, proof that the product is so dangerous and of so little utility that it should not be sold to anyone – or in some jurisdictions, a device may fail to meet consumer expectations, which is in effect just another form of failure to warn.

Even where the plaintiff is not required to prove a safer alternative design, the plaintiff may offer such a design to prove negligence, or unreasonable danger, or whatever similar standard the state may employ. When the plaintiff takes that approach, the need to define the product comes back into play in the same way it does when there is a statutory requirement.

In an early Fourth Circuit case, Driesenstock v Volkswagenwerk A.G., the plaintiff argued that Volkswagen negligently designed a bus because it lacked the safety features of a sedan. The court refused to make that comparison. The court explained the bus could carry cargo while the sedan carried only passengers. As each had its "peculiar purposes", the two vehicles could not be compared, even though both were at times used for passengers.

The Eight Circuit addressed product identity in Linegar v Armour of America Inc. The plaintiff argued a bulletproof vest was unreasonably dangerous because it lacked the protection of a bulletproof jacket. The court refused to make that comparison because each had unique advantages and disadvantages. For instance, the jacket provided more protection, but the vest allowed greater mobility.

In Caterpillar v Shears, Texas law required proof of an economically and scientifically feasible alternative design. The plaintiff contended a front-end loader with a rollover protective structure was defective because the structure could be removed. The Texas Supreme Court stated that, if the structure could not be removed, that would thwart the "intended function" of allowing access to low clearance areas. In a colourful aside, the court stated it would make no sense to say a motorcycle was defective because it did not have four wheels, or to claim a convertible was defective because it did not have a hard top. It was not the purpose of the law, the court said, to eliminate whole categories of useful products from the market.

More recently, the Alabama Supreme Court rejected a claim that an ionisation smoke alarm was unsafe because additional photoelectric technology would have made it safer (Hosford v BRK Brands, Inc.). The court held the combined device would be different "albeit similar". The technologies treated smouldering and flaming fires differently.

In a prescription drug case, limiting alternatives to the same product makes it very difficult to prove design defect because individual drugs carry with them their own advantages and disadvantages even when they treat the same condition. In Brockert v Wyeth Pharm., Inc., the court held an oestrogen-only drug was not a safer alternative design to a drug which combined oestrogen and progestin. Both treated menopausal symptoms, but while one reduced the risk of breast cancer, the other reduced the risk of endometrial hyperplasia. The plaintiff lost because she could not prove her alternative could eliminate both risks.

In Niedner v Ortho-McNeil Pharmaceutical, Inc., the Massachusetts Court of Appeals held an oral contraceptive was not a safer alternative design for a contraceptive patch. The patch only had to be applied once or week, or less, while the oral drug had to be taken at the same time each day.

On the other hand, in Keffer v Wyeth, the court held that a synthetic version of a drug could be a safer alternative for the natural version of the drug. There was no alteration, the court said, of a "fundamental and necessary characteristic of the product".

In the medical device field, courts have routinely held one device is not a substitute for another if the devices require different forms of surgery. In Theriot v Danek, Inc., the Fifth Circuit rejected a claim that pedicle screws used in spinal surgery were defective because the same condition could be treated by an external neck brace or a system of hooks and wires. "The problem with this argument," the court said, was that "it really takes issue with the choice of treatment made by [the plaintiff's] physician, not with a specific fault of the pedicle screw sold by the defendant".

In cases challenging the use of implanted mesh, courts have generally refused to consider alternatives that required a different surgery. In NMI Barnes v Medtronic, PLC., the plaintiff challenged the design of a polyester mesh implant that had been used to treat a hernia. To show gross negligence, the plaintiff pleaded that safer alternatives included surgery without mesh, or mesh made from a cadaver, or polypropylene mesh. The court said these were "alternative categories of products" and not "alternative production practices" for the defendant's product; on that basis, it dismissed the plaintiff's design defect claim.

However, this distinction based on surgery found its limit in a hip implant case, In re DePuy Orthopaedics, Inc. Hip

Implant Product Liability Litigation. The plaintiffs claimed a hip implant which used "cross-linked" plastic to line the socket was a safer alternative to an implant with a metal liner. The court stated products are different if they perform discrete kinds of functions, but not if they do the same things in different "degrees". The defendants argued metal liners both lasted longer and eliminated plastic debris. The plaintiffs countered with evidence that plastic liners were more durable and cross-linking significantly reduced the risk of debris. That was enough, the court stated, to count them as an alternative for the same product.

This emphasis on a precise definition of the product makes sense from several angles.

If a proposed alternative has different advantages and disadvantages, then weighing one against the other is like asking whether an apple tastes better than an orange. The answer depends on too many variables. To take the examples listed above, there is no way to evaluate whether an increase in cargo-carrying capacity is worth a sacrifice of crashworthiness, or whether access to low-clearance areas is worth a loss of rollover protection. The only way to avoid these complexities is to require the alternative be the same product.

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Insisting that the alternative be the same product also ensures the law does not eliminate consumer choice. In this sense, the doctrine is akin to the principle that a manufacturer should not be held liable if it offers a safety option. In Scarangella v Thomas Built Buses, New York's highest court held a bus without a back-up warning was not defective because the purchaser, New York state, was in a position "to balance the benefits and risks". Especially where the manufacturer makes both alternatives, it makes sense to leave the choice to the purchaser, not the jury.

In the medical field, insisting that the alternative be the same product, and not an alternative treatment, keeps product liability law from eliminating choices best made by an informed physician. Medical malpractice law protects physician choice by allowing any alternative treatment as long as "there is a reasonable doubt as to […] the proper course to be followed". The same applies to comment k of the Restatement (Second) of Torts, which eliminates design defect liability where an informed physician choice has been made. The only way to keep design defect law from taking away physician choice is to confine safer alternative design claims to designs for the same product. The only question then will be how best to design the product in question, and not how to best treat the patient, which is something physicians should be free to decide.

As this brief review demonstrates, product identification limits safer alternative design claims, whether those claims arise out of a statute or out of common law. At the same time, the identifying phrases the courts have used leave much room for argument. Standards such as different 'category', different 'purpose', different 'fundamental and necessary characteristic', or different 'surgery' all convey similar ideas, but their vagueness guarantees that litigation over these terms will, if anything, increase in the future.